IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., MERCK KGAA and MERCK PATENT GESELLSCHAFT MIT BESCHRÄNKTER HAFTUNG,	)	
Plaintiffs,	)	C.A. No. 15-272-GMS (consolidated)
v.	)	
ACCORD HEALTHCARE, INC.,	)	
Defendant.	)	

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS, GOLDMAN MCLAUGHLIN & HALL, P.A.
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendant Accord Healthcare, Inc.

Neal C. Belgam (#2721)
Eve H. Ormerod (#5369)
SMITH, KATZENSTEIN, & JENKINS LLP
nbelgam@skjlaw.com
eormerod@skjlaw.com

Attorneys for Defendants Alembic Global Holdings SA, Alembic Pharmaceuticals, Inc. and Alembic Pharmaceuticals Ltd.

Kenneth Laurence Dorsney (#3726)
MORRIS JAMES LLP
kdorsney@morrisjames.com

Attorneys for Defendants Apotex Corp. and Apotex Inc.

R Touhey Myer (#5939)
CAESAR RIVISE, PC
tmyer@crbcp.com

Attorneys for Defendant InvaGen

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
POTTER ANDERSON & CORROON LLP
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyrne@potteranderson.com

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

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1227150 / 42390 (cons.)

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I. INTRODUCTION

Defendants[1] in this Hatch-Waxman patent case seek approval from the U.S. Food and Drug Administration ("FDA") to market generic versions of the drug Viibryd®. Forest[2] alleges that Defendants infringe four Orange Book-listed patents that relate to crystalline forms of the chemical vilazodone hydrochloride ("HCl"), and their use in treating depression and other disorders. Vilazodone HCl is an old compound, well known in the prior art and well known for the treatment of depression and other disorders. The patents-in-suit are U.S. Patent Nos. 7,834,020 (the "'020 patent"), 8,193,195 (the "'195 patent"), 8,236,804 (the "'804 patent"), and 8,673,921 (the "'921 patent"). While Forest maintains that nearly none of the terms in these patents' claims require interpretation, the claims contain ambiguities that can be resolved only through review of the intrinsic evidence, including the patents' specifications and prosecution histories before the U.S. Patent and Trademark Office ("PTO").

II. LEGAL AUTHORITY

Claim language is given the meaning it would have to one of ordinary skill in the relevant art at the time the application was filed, in view of the patent specification. *See Phillips v. AWH Corp*., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). "Each element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent" and "whether the inventor limited the invention in the course of prosecution, making the claim scope narrower

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[1] The "Defendants" are Accord Healthcare, Inc., Alembic Global Holding SA, Alembic Pharmaceuticals Inc., Alembic Pharmaceuticals Ltd., Apotex Inc., Apotex Corp., Teva Pharmaceuticals USA, Inc., and InvaGen Pharmaceuticals Inc.

[2] The "Forest" plaintiffs are Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Merck KGaA, and Merck Patent Gesellschaft mit beschränkter Haftung.

than it would otherwise be." *Phillips*, 415 F.3d at 1317. A court "cannot construe the claims to cover subject matter broader than that which the patentee itself regarded as comprising its inventions and represented to the PTO." *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004). Arguments and amendments made during prosecution "to overcome prior art can lead to narrow claim interpretations because '[t]he public has a right to rely on such definitive statements.'" *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319, 1325 (Fed. Cir. 2002) (quoting *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998)). "The prosecution history constitutes a public record of the patentee's representations concerning the scope and the meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct." *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003).

The Defendants' proposed constructions are the most faithful to the intrinsic evidence and the understanding of a person of ordinary skill in the art.

III. CONSTRUCTIONS OF DISPUTED CLAIM TERMS

A. The Correct Construction of "Administer[ed/ing]" is "Deliver[ed/ing] into the body."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"administer" "administered" "administering"	'020 patent, claim 2 '195 patent, claims 1-2 '804 patent, claim 1 '921 patent, claims 10, 12-14	Plain meaning/no construction required	Deliver[ed/ing] into the body

"[T]he analytical focus of claim construction must begin, and remain centered, on the language of the claims themselves." *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003). Each claim that recites "administer[ed/ing]" is directed to a method of treating a patient. Moreover, several of those claims specify "wherein [a/the] . . . disorder is treated ***in the***

patient." *See* '195 patent, claim 1; '804 patent, claim 1 (emphasis added). Thus, the claimed treatment methods target "disorders" that are "in" the body. The only way to treat a disorder in the body with a pharmaceutical compound is to deliver it into the body. Accordingly, Defendants' construction "delivered [or delivering] into the body" of a patient – is consistent with the ordinary meaning of the terms in the context of the patents-in-suit.

In similar cases, other courts have construed "administer[ed/ing]" to mean delivering into the body. *See, e.g.*, *Andrulis Pharm. Corp. v. Celgene Corp.*, C.A. No. 13-1644-RGA, 2015 WL 3978578 (D. Del. June 26, 2015) (construing "administering" in claimed "method of treatment of neoplastic diseases in a mammal, which comprises administering to said afflicted mammal" as "delivering into or onto a [mammal's] body"), *appeal docket*, No. 15-1962 (Fed. Cir. Sept. 1, 2015); *Medical Research Inst. v. Bioengineering Supplements & Nutrition, Inc.*, No. 605-cv-417, 2007 WL 128937, at *1, 7 (E.D. Tex. Jan. 12, 2007) (construing "administering" in claimed "method of treating atherosclerosis in a human patient" as "delivering the formulation-in-question into a person's body").

The specification further confirms Defendants' construction. The specification discloses several different ways that the claimed drugs may be administered stating that "the Products of the Invention can be formulated into the conventional forms of administration, including peroral and parenteral forms of administration. Tablets or capsules are preferred formulations." '804 patent 15:29-32. The phrases "forms of administration, including peroral and parenteral" and "[t]ablets or capsules" describe routes of administration, or in other words, paths taken by the drug to get ***into the body***.

To the extent that Forest suggests that the plain and ordinary meaning of "administer[ed/ing]" is "provide[ed/ing]," that implicit construction should be rejected. A

disorder cannot be treated merely by "providing" a drug to a patient – the drug must enter into the patient's body. The Court should not adopt a plain and ordinary meaning that implicitly construes the "administer[ed/ing]" terms to encompass the scenario in which a composition containing a pharmaceutical compound is handed or prescribed to a patient suffering from a disorder, but is never taken by the patient and therefore never enters into the body. In such an instance, the disorder was not treated and the claim is not satisfied.

Forest relies on a passage in the specification stating that the "present invention further provides a method for treating and/or preventing any one or more of the Disorders by administering an effective and/or prophylactic amount of the Products of the Invention to a patient in need thereof." '804 patent 15:64-67. However, as explained above, the disorders cannot be treated, nor can a dosage be "effective" or "prophylactic," if the pharmaceutical composition never enters the patient's body. Accordingly, the administer[ed/ing] terms should be construed to mean "deliver[ed/ing] into the body."

B. The Correct Construction of "Effective Amount" is "An Amount of the Specified Crystalline Modification of Vilazodone HCl Sufficient to Produce the Desired Effect."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"effective amount"	'195 patent, claims 1-2 '804 patent, claim 1 '921 patent, claims 13-14	Amount sufficient to promote a therapeutic effect	An amount of the specified crystalline modification of vilazodone HCl sufficient to produce the desired effect

"Effective amount" should be construed to mean "an amount of the specified crystalline modification of vilazodone HCl sufficient to produce the desired effect." In contrast, Forest appears to take the position that "effective amount" relates to the total amount of vilazodone, even if only a minuscule portion is the recited crystalline modification. Forest's argument is incorrect as a matter of law.

In *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc*., 334 F.3d 1274 (Fed. Cir. 2003), the Federal Circuit reviewed a district court's construction of the claim term "effective amount." The Federal Circuit held:

> [T]his court notes that the term "effective amount" has a customary usage. Under this usage, the term would mean "the amount of Lewis acid inhibitor that will prevent the degradation of sevoflurane by a Lewis acid." *See Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1299, 1304 (Fed. Cir. 2002) (affirming the district court's construction of the claim term "effective amount" to mean "a sufficient amount of the specified component to form an encapsulant having the specified properties under the specified conditions, if any").

Id. at 1277-78.

Thus, the customary usage of an "effective amount" means an amount of recited substance sufficient to produce the desired effect. *Id.* In this case, "effective amount" therefore means "an amount of the specified crystalline modification of vilazodone HCl sufficient to produce the desired effect." That is, the specifically recited crystalline modification of vilazodone, must, in itself, be a sufficient amount to bring about the desired effect.

Additionally, the parties dispute what it means to be effective. Defendants assert that an effective amount of the crystalline form is an amount sufficient to *produce* the desired effect, whereas Forest asserts that an effective amount is an amount sufficient to *promote* a therapeutic effect. But, the '804 patent states that "[t]he present invention further provides a method for *treating and/or preventing* any one or more of the Disorders by administering an effective and/or prophylactic amount of the Products of the Invention to a patient in need thereof." '804 patent 15:64-67 (emphasis added). Similarly, claim 1 of the '804 patent recites "A method of *treating* a major depressive disorder, the method comprising: administering to a patient in need thereof a pharmaceutical composition comprising an *effective amount* of . . . [vilazodone] in crystalline modification IV . . . wherein the major depressive disorder is treated in the patient." *See also* '195 patent, claim 1. Thus the claims require the effective amount of the specifically recited

crystalline form of vilazodone itself be sufficient to *treat* the disclosed disorder. The parties have stipulated that "treating" means "attempting to *cause* a therapeutic effect on" and that "is treated in the patient" means "an attempt is made to *cause* a therapeutic effect in the patient." Joint Claim Construction Charts, Ex. A at 1 (D.I. 80-1, May 25, 2016) (emphases added). To "cause" is to "bring[ ] about an effect." Webster's Third New International Dictionary 356 (Merriam-Webster, Inc. 1993). Accordingly, Defendants' proposed claim construction – which recites "to produce" or cause a desired effect – is more accurate than Forest's suggestion that the drug must only be present in an amount sufficient "to promote" (*i.e.*, to encourage) a therapeutic effect.

Forest's proposed definition also leads to illogical results. Take, for example, a tablet containing 10 mg of vilazodone. If 0.01 mg in the tablet is crystalline Form IV vilazodone, and 9.99 mg is a different form, Forest might allege that the 0.01 mg of crystalline Form IV contributes to (and therefore "promotes") the patient's treatment. But this clearly goes against the plain language of claim 1 of the '804 patent, which requires that the crystalline Form IV vilazodone itself be present in an effective amount. Forest would, in essence, have the Court re-write the claim as though it had been written "an effective amount of vilazodone, the vilazodone comprising at least a trace of crystalline Form IV vilazodone."

C. The Correct Construction of "Crystalline Modification" or "Crystalline" is "Entirely in Crystalline Form Comprising Only Form I to XVI, and Combinations Thereof (as Appropriate)."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"crystalline modification" or "crystalline"	'020 patent, claim 1 '195 patent, claim 1 '804 patent, claim 1 '921 patent, claims 1, 5, 11, 13	Crystalline form (for "crystalline modification"), plain meaning/no construction required (for "crystalline")	Entirely in crystalline form comprising only Form I to XVI, and combinations thereof (as appropriate)

"Crystalline modification" or "crystalline" refers to the specific crystalline forms of vilazodone disclosed in the patent and described by the patentees as the "products of the invention." Forest's argument that these terms may encompass other forms, particularly a form that is ***not*** crystalline, belies the plain language of the claims and the prosecution history of the patents.

1. The Claim Language and Specification Support Defendants' Constructions.

Forest concedes that the term "crystalline modification" refers to a crystalline form of vilazodone, but disputes that this term should be construed to only refer to forms of crystalline vilazodone disclosed in the patent. Forest's effort to broaden the scope of the patents-in-suit has no basis in the claim terms or specification.

First, the claim language itself proves that "crystalline" or "crystalline modification" must be referring to the specific forms found by the patentees. As used in claim 1 of the '020 patent, claim 1 of the '804 patent, and claims 5, 11, and 13 of the '921 patent, "crystalline modification," is followed by a Roman numeral, either "IV" or "(V)." In claim 1 of the '020 patent and claim 1 of the '804 patent, the Roman numeral is followed by a parenthetical further stating "(Form IV)." If these references are not to the specific forms found in the patent, as Forest's constructions propose, then these references are simply nonsensical.

Second, the specification, which is shared by all the patents-in-suit, makes it clear that the patents relate to specific forms of crystalline vilazodone. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."). Forest admits that a prior art patent, U.S. Patent No. 5,532,241 (the "'241 patent"), discloses vilazodone specifically as a mixture of amorphous and crystalline HCl salt.

The patent states in the Background that the '241 patent discloses the free base and its conversion to the HCl salt. *See* '921 patent 1:35-57. It also states that "[t]here is no clear teaching elsewhere in the document ['241 patent] of any alternative route or modification to the process which would generate *new crystal modifications of* [vilazodone] or *new solvates* or hydrates of [vilazodone] in different crystal modifications." *Id.* 1:57-64 (emphases added). The patent continues:

> Certain crystalline, i.e. morphological forms of pharmaceutical compounds may be of interest to those involved in the development of a suitable dosage form because if the morphological form is not held constant during clinical and stability studies, the exact dosage used or measured may not be comparable from one lot to the next. . . . Therefore, it is *imperative to assure* that either a single morphological form or some known combination of morphological forms is present.

Id. 2:6-18 (emphasis added).

And the patent relates the term "crystalline modifications" to the terms "solvate," "hydrate," and "anhydrate," stating:

> Accordingly, the present invention provides solvates of [vilazodone] in crystalline modifications and their use." *Id.* 2:44-47.
>
> The present invention furthermore provides [vilazodone] hydrates in crystalline modifications and their use." *Id.* 2:56-59.
>
> The present invention also provides [vilazodone] anhydrates in crystalline modifications and their use." *Id.* 3:1-4.

It therefore follows that the term "crystalline" or "crystalline modifications" refers to the specific solvate, hydrate, and anhydrate polymorphs found in these specific patents. This is not an all-encompassing term covering any crystalline vilazodone HCl.

The patentees summarize the invention as consisting of specific forms of pure crystalline vilazodone designated I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XIII, XIV, XV, and XVI. *See id.* 2:25-40. The patents further state that "[t]hroughout the specification, the term "Form" is generally used as a synonym for the term "modification" or "crystalline modification." *Id.* 2:41-43.

In the detailed description of the invention the "products of the invention" are defined to be the specific forms of crystalline vilazodone described by the patent: Forms I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XIII, XIV, XV, and XVI. *See id.* 14:58-63. As stated by the Federal Circuit:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (internal citation omitted). Because the patents-in-suit plainly state that these specific forms of crystalline vilazodone are the invention covered by the patents, the claims should be construed to only cover those crystalline forms.

2. The Prosecution Histories Support Defendants' Construction.

The prosecution histories of the patents-in-suit establish that the patentees considered their invention to be limited to the specific, disclosed forms of crystalline vilazodone.

a. Prosecution History of the '020 Patent.

The PTO rejected the central claim of the '020 patent, claim 1, as anticipated by the '241 patent. In rejecting the claim, the PTO stated that the applicants admitted that the '241 patent disclosed in its Example 4 a mixture of amorphous and crystalline vilazodone HCl. *See* '020 patent history, 4/28/2008 Office Action Summary at 5 (VB0000271); '020 patent 1:50-57. To overcome this rejection, the patentees amended claim 1 to specifically recite the Form IV polymorph of vilazodone HCl, and deleted a reference to amorphous 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. *See* '020 patent history, 3/18/2010 Reply (VB0000253-262). On this basis, the PTO allowed the claims. *See* '020 patent

history, 4/28/2008 Notice of Allowance and Fee(s) Due (VB0000212-214); '020 patent history, 6/18/2010 Notice of Allowability (VB0000215-217).

b. Prosecution History of the '195 Patent.

The PTO rejected certain claims of the '195 patent on various grounds, including obviousness-type double patenting. '195 patent history, VB0000797-811. But the PTO also allowed certain claims that recited specific forms of crystalline vilazodone, stating:

> The closest prior art is considered to be US 5532241, issued 07/02/1996. It discloses 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride at col. 11, Example 4. The '241 Patent, however, *fails to teach or suggest a crystalline form* of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride. Therefore, the '241 Patent fails to anticipate or render obvious claims *reciting specific crystalline forms* of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride.

'195 patent history, 11/12/2010 Office Action Summary at 13-14 (VB0000810-11).

c. Prosecution History of the '804 Patent.

The PTO rejected claim 1 of the '804 patent as anticipated by the '241 patent. *See* '804 patent history, 5/4/2011 Office Action Summary (VB0001387-1396). The PTO stated that the '241 patent disclosed the use of crystalline vilazodone in treating depressive disorders, stating "['241 patent] teaches a method of using the compound 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine in its crystalline HCl salt, monohydrate, hemihydrate[,] or composition form." *Id.* at 5-6 (VB0001392-93). In its response, applicant did not refute the PTO's assertion that the '241 patent disclosed a crystalline HCl salt of vilazodone, and the applicant instead amended claim 1 to recite a particular polymorph (Form IV) of crystalline vilazodone, as well as citing the specific characteristic peaks of the polymorph. *See* '804 patent history, 2/9/2012 Amendment and Response to Non-Final Office Action at 2 (VB0001298).

Applicant stated specifically that "the '241 patent fails to teach or suggest the polymorphic form IV as set forth in the amended claims." *Id.* at 4 (VB0001300).

d. Prosecution History of the '921 Patent.

In allowing the claims of the '921 patent, the PTO again identified the '241 patent as the closest prior art, but allowed the claims because the '241 patent did not teach the specific forms being claimed by applicants:

> The closest prior art is U.S. Patent no. 5,532,241, which does not teach the *claimed crystalline forms*. This reference does not encompass the scope of the instant application. This reference *lacks [the] identical or obvious crystalline forms* of 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine. A person of ordinary skill in the art would not have expected that making modifications would retain identical activity as disclosed in the prior art.

'921 patent history, 12/2/2013 Notice of Allowability at 2 (VB0001687).

e. Forest May Not Seek To Have the Claims Construed More Broadly Than the Positions Taken During Prosecution.

As set forth above, during prosecution of the patents-in-suit, the PTO repeatedly confirmed that only the specific forms of crystalline vilazodone were patentable over the '241 patent's general disclosure of crystalline vilazodone, and rejected claims as either anticipated or obvious due to the '241 patent if stated in more general terms. At no point did patentees contest the PTO's rejections on these grounds, and in fact they often amended the claims to identify an individual form identified by its Roman numeral. Forest may not now seek to expand the scope of the claims to encompass forms not disclosed in the patent, as that position is contrary to the position it maintained to achieve approval by PTO. *See Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1382 (Fed. Cir. 2000) (plaintiff may not rely on specific descriptions of its invention to distinguish itself from prior art, then later construe its claims more broadly during an infringement action).

D. The Correct Construction of "Exhibits the Following XRD Data" is "Must Show All the Following Peaks and Intensities."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"exhibits the following XRD data"	'020 patent, claim 1	Displays X-ray diffraction pattern consistent with the following values, with experimental error ranges (e.g., +/- 0.1° for two-theta values)	Must show all the following peaks and intensities

Forest is attempting to read the claimed peak intensities entirely out of the claim and to insert indefinite terms of approximation ("consistent with" and "e.g., +/- 0.1° for two-theta values") into the claim through claim construction. However, the prosecution history of the '020 patent clearly indicates to one of ordinary skill in the art that "exhibits the following XRD data" means "must show all the following peaks and intensities" and that claim 1 was not intended to include approximations to those specific, recited peak and intensity values. Specifically, "exhibits the following XRD data" does not mean merely displaying X-ray diffraction pattern "*consistent with* the following values, with experimental error ranges (e.g., +/- 0.1° for two-theta values)," as Forest proposes, and it must include the recited peak intensities. "[C]onsistent with" is an indefinite term that opens up the specific, recited peak and intensity values to approximations.

To overcome the examiner's rejection of claim 1 of the '020 patent as anticipated by the '241 patent, the patentees amended the claim – which originally did not list X-ray data peaks – to recite:

> A compound which is 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in crystalline modification IV (Form IV), wherein said compound *exhibits the following XRD data*:

No.	d (Å)	2θ	I/I_0
1	9.732	9.08	22
2	6.885	12.85	10
3	6.102	14.50	22
4	5.246	16.89	9
5	4.695	18.89	100
6	4.344	20.43	20
7	4.088	21.72	12
8	3.615	24.61	67
9	3.258	27.35	17
10	3.164	28.18	12

'020 patent history, 3/18/2010 Reply (VB0000253-262); *see also* '020 patent history, 9/23/2009 Supplemental Election and Amendment (VB0000314-329). Claim 1 was then allowed based on this amendment. *See* '020 patent history, 6/18/2010 Notice of Allowability (VB0000215-217). The patentee later attempted to further amend claim 1 of the '020 patent to read: "exhibits *approximately* the following XRD data." '020 patent history, 8/18/2010 Amendment Under 37 C.F.R. 1.312 at 1-6 (VB0000203-209) (emphasis added). But the patentee withdrew this amendment prior to comment by the examiner. *See* '020 patent history, 9/4/2010 Withdrawal of Amendment Under 37 C.F.R. 1.312 (VB0000191).

These amendments make clear that the listed peak and intensity values should be construed as precise values. The patentee obtained a patent over the prior art only by including these specific, recited data points. Moreover, the patentee's failed attempt to amend the claim to include the term "approximately" not only proves that the claim, as allowed, is directed to the specific, recited peaks and intensity values, but verifies that the patentee ultimately affirmatively chose not to claim them "approximately." Forest cannot now use claim construction to rewrite those decisions.

Further evidence of the patentee's and examiner's understanding of the scope of claim 1 of the '020 patent can be found in the prosecution of application no. 13/100,948 (the " '948 application"), which shared a common examiner with the '020 patent. As explained in detail, *see supra* Part III.E., the phrase "corresponding to" means matching the precise values recited in the

claims. The ’948 application included claims requiring peaks with values “corresponding to” specific, recited values. The examiner issued a final rejection of those claims in the ’948 application for statutory double patenting over claim 5 of the ’020 patent. *See* ’948 application at 3-6 (VB0001286-1289). As pointed out by the examiner in his final rejection,

> Despite the differences in claim language, Applicant’s claims 1, 25 and 26 [of the ’948 application] are drawn to the same disorder in the method of treating, i.e. major depressive disorder, and *the same compound is used*, i.e. 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride anhydrate in crystalline modification IV (Form IV*). The instantly claimed characteristic XRD peaks are exactly the same XRD peaks depicted in claim 1 of the ’020 Patent*. Therefore, the claims are drawn to the same invention.

See id. at 5-6 (VB0001288-1289) (emphases added). The patentee did not dispute that the scope of the claimed XRD peaks in claim 1 of the ’020 patent and claims 1, 25, and 26 of the ’948 application were “exactly the same.” *Id.*; *see also* ’804 patent history, 5/4/2011 Amendment and Response to Final Office Action at 4 (VB0001275).

Forest’s inclusion of the phrases “consistent with” and “e.g., +/- 0.1° for two-theta values” in its proposed construction of claim 1 of the ’020 patent ignores this prosecution history and attempts to inject elements of approximation into the recited peak and intensity values that are clearly not part of claim as written and allowed. Forest cannot, on the one hand, limit the claim to precise values to overcome a rejection during prosecution[3] and, on the other hand, broaden the scope of those claimed values during litigation to recapture approximate values. *See Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

[3] Or to overcome a statutory double patenting rejection in the case of the ’948 application/’804 patent.

E. The Correct Construction of "Corresponding to" is "Matching the Precise Values Recited in the Claims."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"corresponding to"	'804 patent, claims 1-3	Consistent with	Matching the precise values recited in the claims

"Corresponding to" should be construed to mean "matching the precise values recited in the claims." Forest's construction provides no guidance, broadens the scope of the claim beyond its plain meaning, and attempts to reintroduce the exact type of indefinite language that the examiner rejected. The prosecution history makes clear that Forest's construction would not only render the claims indefinite, but that such a construction was clearly surrendered in order to obtain allowance of the claims.

The prosecution history of application no. 12/566,835 (the "'835 application"), which is the parent to the '804 patent, leaves no doubt that "corresponding to"[4] means "matching the precise values recited in the claims." Claim 60 of the '835 application was originally drafted to recite a particular vilazodone HCl polymorphic form with "characteristic peaks at 2Theta values *of approximately* 9.34, 10.83, 13, 13.47, 18.7, 19.44, 20.09, 20.98, 25.41, and 26.13 degrees." '835 application, 9/22/2010 Reply at 11 (emphasis added). The examiner rejected claim 60 under 35 U.S.C. § 112(2), stating that "***the peaks should be claimed definitely and not use approximations***" and specifically explained that the patentees could "***overcome this rejection by inserting the peaks found in claim 60 and omitting any indefinite terms such as***

[4] During prosecution of the '804 patent, claim 1 was amended to include the term "corresponding to" and claims 25 and 26, which included the term "corresponding to" were added. *See* '804 patent history, 2/9/2012 Amendment and Response to Non-Final Office Action at 1-5 (VB0001297-1301). Claims 1, 25, and 26 issued as claims 1, 2, and 3 respectively in the '804 patent. Nothing in the prosecution of the '804 patent contradicts the prosecution of the parent '835 application with respect to the term "corresponding to."

approximately." '835 application, 10/8/2010 Office Action Summary at 2-3 (emphases added). In response, the patentee amended claim 60 to recite the particular vilazodone HCl polymorph form "having characteristic peaks at 2Theta values ***corresponding to*** 9.34, 10.83, 13.00, 13.47, 18.70, 19.44, 20.09, 20.98, 25.41 and 26.13 degrees." *See* '835 application, 2/8/2011 Amendment and Response to Final Office Action at 2 (emphasis added). The patentee explained, "[w]ith respect to claims 1 and 8, Applicant has replaced the term 'about' with 'corresponding to' in order to expedite prosecution." *Id* at 6. Furthermore, the patentee explained:

> Claims 60-69 were rejected under 35 USC § 112, second paragraph as being indefinite for the recitation of the terms "approximately," "within about 0.1 degrees" and "plus/minus 0.1 degrees." Applicant notes that claims 61, 65, 67 and 68 are canceled by this amendment. In claims 60, 62 and 63, Applicant has replaced the term "approximately" with "corresponding to" in order to expedite prosecution.

Id. The claims, as amended to overcome the § 112 second paragraph rejection, were allowed. *See* '835 application, 3/11/2011 Notice of Allowance and Fee(s) Due.

In sum, the examiner rejected the use of the indefinite terms, including "about" and "approximately," under § 112 second paragraph and instructed that "the peaks should be claimed definitely and not use approximations." The claims were not allowed until the patentees replaced those indefinite terms with "corresponding to," thereby definitely claiming the specific values recited in the rejected claims.

Forest's proposed construction of the term "corresponding to" as "consistent with" is akin to construing "corresponding to" to mean "about" or "approximately." Accordingly, if Forest's construction is adopted, then claims 1-3 of the '804 patent will be rendered indefinite. Moreover, Forest followed the examiner's instruction to "overcome [the] rejection by inserting the peaks . . . and omitting any indefinite terms such as approximately" by amending the claims

to include the term "corresponding to." In doing so, Forest limited the claim scope to peaks "matching the precise values recited in the claims." Forest should not be allowed to limit the scope of a claim to precise values to overcome an indefiniteness rejection during prosecution only to broaden the scope of those claimed values during litigation to recapture the "approximations" it disclaimed to obtain allowance. *See Southwall Techs.*, 54 F.3d at 1576. This Court should reject Forest's attempt to regain claim scope that it surrendered during prosecution.

F. The Correct Construction of "Characteristic Peak[ ]" is "A Powder XRD Peak Having Intensity ≥ 3*noise, Which Serves to Identify the Crystalline Modification."

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"characteristic peak[ ]"	'804 patent, claims 1-3	Peak representative of a crystalline form's X-ray diffraction pattern	A powder XRD peak having intensity ≥ 3*noise, which serves to identify the crystalline modification

The parties appear to agree that a characteristic X-ray diffraction peak serves to identify, or is representative of, a specific crystalline modification. In claim 1, the characteristic peaks are selected from peaks having specific two-theta values. A characteristic peak, however, is not simply defined by its position (its two-theta value). As the '804 patent itself uses the term, a characteristic peak has a two-theta value *and* a minimum intensity. The '804 patent discloses that the minimum intensity of a characteristic peak is greater than or equal to three times the noise level. Forest's proposed construction is incorrect because it ignores the intensity values of the characteristic peaks.

Table III of the '804 patent, lists data for powder X-ray diffraction patterns for sixteen polymorphic forms. For each polymorphic form in Table III (except for Form XIV), data for ten characteristic peaks are identified. For Form XIV, however, data for only seven characteristic

peaks are disclosed, as data for peaks 8, 9, and 10 are omitted. '804 patent 26:47-49. The '804 patent discloses that data for peaks 8, 9, and 10 are omitted because "[f]urther peaks exhibit intensities <3*noise." *Id.* 27:11. In other words, for a peak to be considered a "characteristic peak[]" in the '804 patent, the peak must have an intensity that is not less than three times the noise level. Based on Table III, a peak less than 3 times the noise level would not be considered a "characteristic peak[]." *Id.* 26:47-49.

The specification thus excludes peaks that are too weak to significantly stand above the background noise. Accordingly, Defendants' proposed construction should be adopted, *i.e.*, a "characteristic peak[]" is "a powder XRD peak having intensity ≥3*noise, which serves to identify the crystalline modification."

G. Preambles are Not Limiting.

Claim Term	Patent & Claim	Forest's Construction	Defendants' Construction
"A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome, undesired puerperal lactation, or combinations thereof"	'020 patent, claim 2 '921 patent, claims 10, 12-14	Entire preamble is limiting	"A method of treating," is not limiting

The "preamble" of the claim – which appears before the word "comprising" – is normally not a limitation that needs to be met for the claim to be infringed or invalidated. *See Aspex Eyeware, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012). Specifically, a preamble is "not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'"

Braintree Labs., Inc. v. Novel Labs., Inc., 749 F.3d 1349, 1357 (Fed. Cir. 2014) (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)). In some circumstances, a portion of a preamble may limit the scope of the claims, while another portion of the same preamble may be non-limiting. *See, e.g.*, *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1322-24 (Fed. Cir. 2015). Here, one portion of the claims' preamble ("[a] method of treating") is not limiting, but the other portion ("a patient suffering from") is limiting. Nothing in the disputed portion of the preamble ("[a]method of treating") provides additional required action, structure or conditions; this phrase only recites a statement of purpose.

The portions of the disputed preambles ("[a] method of treating") state the *purpose* of the alleged inventions – to treat a patient – and are not necessary elements of the claims because the body of the claim otherwise recites a complete method. "If the body of the claim sets out the complete invention, the preamble is not ordinarily treated as limiting the scope of the claim. However, the preamble is regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) (internal citation omitted). In a method claim, such essential structure might be additional steps of the method. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Here, the term "[a] method of treating" in the disputed preambles does not set forth additional steps, indicating that it should not be construed as a limitation. The bodies of the claims are structurally complete, even in the absence of the disputed preamble language.

Language in a preamble may be limiting when it provides an antecedent basis for limitations appearing in the body of the claim. *See id.* Here, the body of the disputed preambles refers to administering a compound to "said patient," or "the patient in need." *See* '020 patent

28:18-19; '921 patent 28:2-3, 18-19, 29-30, 42-43. The language from the preambles beginning with "a patient" provides antecedent basis for the references to a "patient" in the body of the claims. However, the language from the preambles before "a patient" ("[a] method of treating"), which is merely a statement of purpose, should not be considered limiting.

The Federal Circuit recently addressed a similar situation. In *TomTom*, the claim at issue included a preamble that read as follows:

> A method for generating and updating data for use in a destination tracking system of at least one mobile unit comprising.

790 F.3d at 1318. The Federal Circuit held that while the phrase "a destination tracking system of at least one mobile unit" was a limitation because it provided antecedent support for limitations appearing in the body of the claim, the remainder of the preamble ("[a] method for generating and updating data for use in") was not:

> That the phrase in the preamble "destination tracking system of at least one mobile unit" provides a necessary structure for claim 1 does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention. Thus, the generating language is not limiting and does not provide an antecedent basis for any of the claims. Rather, it is language stating a purpose or intended use and employs the standard pattern of such language: the words "a method for a purpose or intended use comprising," followed by the body of the claim, in which the claim limitations describing the invention are recited.

Id. at 1323-24. Defendants respectfully propose that "[a] method of treating" as stated in the preambles is not limiting for the same reason.

IV. CONCLUSION

The Court should adopt Defendants' proposed constructions for the disputed terms of the '020, '195, '804, and '921 patents.

Respectfully submitted,

PHILLIPS, GOLDMAN MCLAUGHLIN & HALL, P.A.

By: */s/ David A. Bilson*
John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
1200 North Broom Street
Wilmington, DE 19806
Tel: (302) 655-4200
Fax: (302) 655-4210
jcp@pgmhlaw.com
dab@pgmhlaw.com

Attorneys for Defendant Accord Healthcare, Inc.

OF COUNSEL;

Paul A. Braier
Michael J. Fink
Neil F. Greenblum
P. Branko Pejic
Jill Browning
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Pl. # 100
Reston, VA 20191
Tel: (703) 390-1298
Fax: (703) 716-1180
pbraier@gbpatent.com
mfink@gbpatent.com
ngreenblum@gbpatent.com
bpejic@gbpatent.com
jbrowning@gbpatent.com

SMITH, KATZENSTEIN, & JENKINS LLP

By: */s/ Eve H. Ormerod*
Neal C. Belgam (#2721)
Eve H. Ormerod (#5369)
The Brandywine Building
1000 West Street, Suite 1501
P.O. Box 410
Wilmington, DE 19899
Tel: (302) 652-8400
Fax: (302) 652-8405
nbelgam@skjlaw.com
eormerod@skjlaw.com

Attorneys for Defendants Alembic Global Holdings SA, Alembic Pharmaceuticals, Inc. and Alembic Pharmaceuticals Ltd.

OF COUNSEL:

Jay R. Deshmukh
KNOBBE, MARTENS, OLSON & BEAR, LLP
1717 Pennsylvania Avenue, NW, Suite 900
Washington, DC 20006
Tel: (202) 640-6400
Fax: (202) 640-6401
jay.deshmukh@knobbe.com

William O. Adams
Karen M. Cassidy
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel: (949) 760-0404
Fax: (949) 760-9502
william.adams@knobbe.com
karen.cassidy@knobbe.com

OF COUNSEL:

Stephen R. Auten
Richard T. Ruzich
Ian Scott
Roger Kiley
TAFT STETTINIUS & HOLLISTER LLP
Tel: (312) 527-4000
Fax: (312) 527-4011
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
sauten@taftlaw.com
rruzich@taftlaw.com
iscott@taftlaw.com
rkiley@taftlaw.com

MORRIS JAMES LLP

By: */s/ Kenneth Laurence Dorsney*
Kenneth Laurence Dorsney (#3726)
500 Delaware Avenue, Suite 1500
P.O. Box 2306
Wilmington, DE 19899-2306
Tel: (302) 888- 6855
Fax: (302) 571-1750
kdorsney@morrisjames.com

Attorneys for Defendants Apotex Corp. and Apotex Inc.

OF COUNSEL:

Robert S. Silver
Salvatore Guerriero
Lynn Terrebonne, Ph.D.
Pei-Ru Wey, Pharm. D.
CAESAR RIVISE, PC
7 Penn Center, 12th Floor
1635 Market Street
Philadelphia, PA 19103-2212
Tel: (215) 567-2010
Fax: (215) 751-1142
rsilver@crbcp.com
sguerriero@crbcp.com
lterrebonne@crbcp.com
pwey@crbcp.com

CAESAR RIVISE, PC

By: */s/ R. Touhey Myer*
R Touhey Myer (#5939)
King Street Plaza, Suite 304
800 North King Street,
Wilmington, DE 19801
Tel: (302) 544-9100
Fax: (302) 544-9103
tmyer@crbcp.com

Attorneys for Defendant InvaGen

OF COUNSEL:

J.C. Rozendaal
Michael E. Joffre
Miles J. Sweet
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, NW, Suite 400
Washington, DC 20036
Tel: (202) 326-7900
Fax: (202) 326-7999
jrozendaal@khhte.com
mjoffre@khhte.com
msweet@khhte.com

Dated: June 22, 2016
1227150 / 42390 (cons.)

POTTER ANDERSON & CORROON LLP

By: */s/ Bindu A. Palapura*
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
Fax: (302) 658-1192
dmoore@potteranderson.com
bpalapura@potteranderson.com
sobyrne@potteranderson.com

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.